Remarks

The Office Action mailed September 30, 2008 has been received and reviewed. Claims 1-52 are pending, of which claims 1-16, 29-38, and 52 are under consideration. Claims 12-14, 29, 38, and 52 are amended. Reconsideration and withdrawal of the rejections are respectfully requested.

Claim Amendments

Claims 12 and 38 are amended to correct obvious typographical errors.

Claim 13 is amended to conform to claim 12, from which claim 13 depends.

Claim 14 is amended so that it is written in independent form.

Claim 29 is amended to recite, in part, analyzing the cell for a polypeptide that, among other features, is recognized by an antibody that specifically binds to a polypeptide comprising the amino acid sequence depicted in SEQ ID NO:1. Support for the amendment may be found in Applicants' specification at, for example, paragraphs [0069] and [0092].

Claim 52 is amended to recite that the isolated antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1, or an immunogenic fragment thereof. Support for the amendment may be found in Applicants' specification at, for example, paragraphs [0122], [0069], and [0070].

Objection to Claim

Claim 12 is objected to as containing a grammatical error. Claim 12 is amended, obviating the objection. Applicants respectfully request that the objection to claim 12 be withdrawn.

The 35 U.S.C. §112, Second Paragraph, Rejection

Claims 13, 14, 16, 29-38, and 52 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 13 is rejected as having no antecedent basis for the term "immunogenic subunit." Claim 13 is amended. obviating the rejection.

Claims 14 and 16 are rejected as being vague for reciting that the method includes "making a monoclonal-antibody producing hybridoma using the cell." The Office Action asserts that making a hybridoma is not a method of isolation. Claim 16 is rejected for being dependent from claim 14. Claim 14 is rewritten in independent form, obviating the rejection.

Claim 29 is rejected as being vague and indefinite for reciting "analyzing," "ER-α36," and "ER-α36 activity." Claims 30-38 are rejected as being dependent from claim 29. Applicants respectfully traverse the rejection.

Claim 29 is amended to delete reference to "ER-α36" and "ER-α36 activity," thereby obviating the rejection with respect to the use of those terms.

The Office Action states that it is unclear how the recited step of "analyzing" is to be performed "since 'analyzing' is considered a mental or cognitive activity." (Office Action, page 4). Applicants respectfully traverse.

Applicants use the term "analyzing" in the sense of performing an analytical method and, as such, "analyzing" should not be construed as merely a mental or cognitive activity. Applicants' specification describes how exemplary analytical methods may be performed at, for example, paragraphs [0092] and [0093] of U.S. Patent Application Publication No. US 2007/0258895 A1 (all references to locations in Applicants' specification refer to locations in U.S. Patent Application Publication No. US 2007/0258895 A1). Therefore, Applicants submit that it is clear to one skilled in the art how the step of "analyzing the cell" is to be performed.

Consequently, Applicants respectfully submit that claims 29-38 satisfy the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection of claims 29-38 as being indefinite be reconsidered and withdrawn.

Claim 30 is rejected as being vague for reciting providing a cell *ex vivo*. Claim 33 is rejected as being vague for reciting providing a cell *in vivo*. The Office Action states that it is unclear how providing a cell could be anything other the providing the cell *ex vivo* and,

consequently, it is also unclear how one can provide a cell if the cell is *in vivo*. (Office Action. page 5). Applicants respectfully traverse the rejection.

The rejected claims depend from claim 29, which is drawn to a method that includes "providing a cell." Nothing in claim 29 requires that the cell be isolated in any manner from its source. Thus, it should be clear that one can provide a cell *ex vivo* (with respect to claim 30) by removing the cell from a subject or provide the cell *in vivo* (with respect to claim 33) as a component of an organism. Applicants specification describes providing cells *ex vivo* and providing cells *in vivo*–i.e., as a component of a subject such as, for example, in an organ or a tumor–at, for example, paragraph [0091].

Applicants respectfully submit that claims 30 and 33 satisfy the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection of claims 30 and 33 as being indefinite be reconsidered and withdrawn.

Claim 52 is rejected as reciting a kit, but failing to recite two or more elements and the interrelationship between the elements. Applicants respectfully traverse the rejection.

Applicants respectfully submit that there is no authority that requires a kit claim to include two or more components and to explicitly state the interrelationship of those components, as suggested in the Office Action. The Office Action cites *In re Venezia*, 530 F.2d 956, 189 USPQ 149 (CCPA 1976) in support of its position that a kit claim, by definition, requires recitation of two or more elements and an explicitly stated interrelationship between the elements. *In re Venezia* provides no such authority. The kit claims in *In re Venezia* were drawn to a kit for a splice connector that was to be assembled in the field to provide a splice connection between a pair of high voltage shielded electrical cables. 189 USPQ 150. The question before the CCPA in *In re Venezia* was whether language in the claims referring to assembly of the components in the field sufficiently defined the metes and bounds of the structure of the recited components. The CCPA ruled that the recitation of the interrelationships between components defined adequate structure to satisfy 35 U.S.C. §112, second paragraph. However, in contrast to the position set forth in the Office Action, the CCPA did not require that a kit claim include two or more components. The CCPA stated, "We see nothing wrong in defining structures...in terms

of the interrelationship of the components, or the attributes they must possess, in the completed assembly...One skilled in the art would have no difficulty determining whether or not a particular collection of components infringed the collection of interrelated components defined by these claims." *Id.*, 152. The CCPA permits drafting kit claims based on the interrelationship of components, it does not require one to do so.

Claim 52 recites a kit that includes, in part, an isolated antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1. A cursory search using the USPTO website identifies numerous recently issued patents containing kit claims that do not include two or more components or any explicitly stated interrelationship between components. Many of these issued kit claims are similar to claim 52 in general format: A kit comprising the antibody/monoclonal antibody/polypeptide of X, with X often being reference to a preceding claim that includes a SEQ ID NO. Examples include:

- U.S. Pat. Nos. 7,446,180, claim 3: "A kit for detecting or isolating truncated forms of human tau protein in a sample of brain tissue or body fluid comprising a DC-11 or DC-11/I antibody as produced by hybridoma cell line DC-11 (ECACC Deposit No: 00082215) or DC-11/I (ECACC Deposit No: 00082216)." (emphasis added);
- 7,446,178, claim 8: "A kit comprising the antibody of claim 1.";
- 7,442,516, claim 3: "A reagent kit for detecting Alzheimer's disease comprising at least the antibody as claimed in claim 1." (emphasis added);
- 7,438,908, claim 13: "A diagnostic kit comprising the antibody or fragment of claim 1.";
- 7,435,590, claim 3: "A kit for detecting a human tumor comprising the monoclonal antibody according to claim 2."; and
- 7,432,358, claim 2: " A kit for an antigen-antibody reaction comprising the antibody of claim 1, wherein the antibody is used to detect an oncogenic protein consisting of the amino acid sequence of SEQ ID NO:1 or a peptide fragment comprising amino acids 50 to 66: CNFKPDIQEIPKKPKVEE of the amino acid sequence of SEQ ID NO:1 which peptide fragment is derived from the oncogenic protein." (emphasis added).

Some of these claims include further definition of the antibody or polypeptide, but none of the

listed recently issued kit claims includes a second component and, therefore, none expressly states any interrelationship between two or more components.

The ultimate question for the CCPA in *In re Venezia* was whether one skilled in the art can determine whether a particular kit in question would infringe the kit defined in an asserted kit claim. Applying that standard to claim 52, Applicants respectfully submit that one skilled in the art can readily determine whether an isolated antibody binds to an amino acid sequence depicted at SEQ ID NO:1 and, therefore, whether any kit in question would infringe claim 52.

Applicants respectfully submit that claim 52 satisfies the requirements of 35 U.S.C. §112, second paragraph, and request that the rejection be reconsidered and withdrawn.

The 35 U.S.C. §102 Rejection

Claims 1-16 and 52 stand rejected under 35 U.S.C. §102(e) as being anticipated by U.S. Patent Application Publication No. US 2007/0015271, filed April 27, 2003 (Rosen). Applicants respectfully traverse.

Claims 1, 12, and 52 are independent. Each of claims 2-11 depends, directly or indirectly, from claim 1. Each of claims 13-16 depends, directly or indirectly, from claim 12. Each of the dependent claims includes all of the features recited in the claim or claims from which it depends. Consequently, remarks that refer to one or more independent claims apply equally to any claim that depends from a referenced independent claim.

Claim 1 is drawn to an isolated antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1 or an immunogenic fragment thereof. Claim 12 is drawn a method of making an antibody that specifically binds to an amino acid sequence depicted at SEQ ID NO:1 or an immunogenic fragment thereof. Claim 52 is drawn to a kit that includes such an antibody.

The Office Action states that Rosen teaches SEQ ID NO:5141, a 111 amino acid polypeptide that includes a six amino acid fragment–amino acids 90-95–that is 100% identical to amino acids 11-16 of SEQ ID NO:1 recited in claim 1. (Office Action, page 6). The Office Action further states that Rosen teaches antibodies to the polypeptides described in Rosen,

including the polypeptide depicted in SEQ ID NO:5141. *Id.* The Office Action concludes that this teaching anticipates claim 1 because an antibody that would bind to amino acids 90-95 of SEQ ID NO:5141 would also bind to amino acids 11-16 of Applicants' SEQ ID NO:1. *Id.*

MPEP §2131 states, "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Applicants respectfully submit that Rosen cannot anticipate claims 1, 12, and 52 because Rosen fails to set forth each and every feature recited in claims 1, 12, and 52. Specifically, contrary to the position set forth in the Office Action, Applicants submit that Rosen fails to teach and antibody that specifically binds to an amino acid sequence of Applicants' SEQ ID NO:1 or an immunogenic fragment thereof.

As stated in the Office Action, Rosen teaches a polypeptide–SEQ ID NO:5141–and generally, albeit thoroughly, teaches the production of antibodies that can specifically bind a described polypeptide. However, Rosen fails to expressly describe an antibody that binds specifically to a polypeptide having the amino acid sequence of SEQ ID NO:5141. Moreover, Rosen fails to describe an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. Therefore, the validity of the rejection hinges on whether Rosen inherently teaches an antibody that binds to amino acids 90-95 of SEQ ID NO:5141.

The Federal Circuit and its predecessor have both held that inherent anticipation occurs only when descriptive material that is not expressly described in a prior art document is necessarily disclosed–not merely possibly or even probably disclosed–in the prior art document. "Inherency ... may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." In re Oelrich, 666 F.2d 578, 581, 212 USPQ 323, 326 (CCPA 1981). "Inherent anticipation requires that the missing descriptive material is 'necessarily present,' not merely probably or possibly present, in the prior art." Trintec Indus., Inc. v. Top-U.S.A. Corp., 295 F.3d 1292, 1295, 63 USPQ2d 1597, 1599 (Fed. Cir. 2002) (quoting In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999)).

The teaching of Rosen fails to expressly describe an antibody that specifically binds to

amino acids 90-95 of Rosen's SEQ ID NO:5141. Thus, such an antibody must be necessarily disclosed by the teaching of Rosen in order for Rosen to inherently describe the antibody recited in Applicants' claims 1, 12, and 52. However, the teaching of Rosen amounts to no more than a possibility or probability of producing an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. If one skilled in the art were to attempt to generate antibodies against a polypeptide having the amino acid sequence of Rosen's SEQ ID NO:5141, the skilled person would not necessarily produce an antibody that specifically binds to amino acids 90-95 of SEQ ID NO:5141. Consequently, Rosen fails to set forth teaching that inherently discloses an antibody that specifically binds to Applicants' SEQ ID NO:1 or an immunogenic fragment thereof.

Because Rosen neither expressly nor inherently sets forth each and every feature recited in Applicants' claims 1, 12, and 52, Rosen cannot anticipate those claims. Applicants therefore respectfully submit that claims 1-16 and 52 are novel over Rosen and request that the rejection of claims 1-16 and 52 under 35 U.S.C. §102(e) as being anticipated by Rosen be reconsidered and withdrawn.

Summary

Applicants respectfully submit that claims 1-16, 29-38, and 52 are in condition for allowance and notification to that effect is respectfully requested. The Examiner is invited to contact Applicant's Representatives at the telephone number listed below if it is believed that prosecution of this application may be assisted thereby.

Respectfully submitted
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